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10/540,829	02/21/2006	Ganugapati Vijaya Bhaskar	DAIRY88.011APC	2247

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EXAMINER
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BADR, HAMID R

ART UNIT	PAPER NUMBER
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1781

NOTIFICATION DATE	DELIVERY MODE
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01/05/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/540,829	<b>Applicant(s)</b> BHASKAR ET AL.	
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1781	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' amendment filed 11/12/2010 is acknowledged.

Rejection of claims 1-10, 12 and 14 under 35 U.S.C. 112 second paragraph is withdrawn due to amendments by applicants.

The declaration by Mr. Skelt Gerald Anema, dated 11/12/2010, has been considered.

Claims 1-19 and 21-26 are being considered on the merits.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Delespaul et al. (FR 2 452 879; Official Translation; hereinafter R1).

3. R1 discloses a process for making cheese. It specifically discloses a process for preparing milk products with improved texture. In classical cheese making, a coagulation stage is used where the milk is coagulated using an acid, pressure or notably microbial enzymes. (page 2, first and second paragraphs).

4. R1 discloses that a more recent technique is the cheese making process by ultrafiltration consisting of concentrating milk proteins using membranes. (page 2, paragraph 3). Since R1 is disclosing a concentration process, the milk product retained

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on the filter (retentate) is a milk protein concentrate (MPC) which contains caseins and whey proteins.

5. R1 discloses that the proteinaceous concentrate is coagulated by adding enzymes (rennet) and can be acidified by chemical acidification or bacteriological acidification (bacterial lactic fermentation) and by pressure to obtain cheese. The obtained cheese can undergo classical operations of acidification and aging. (page 2, last paragraph).

6. R1 teaches of heating the milk before the ultrafiltration process or heating the retentate of the ultrafiltration process to temperatures which can reach sterilization. This thermal treatment is effectuated at 75-150C and allows obtaining cheeses having fine and homogenous texture. R1 further explains that one can attribute the favorable effect of the heat treatment to partial denaturation of proteins or modification of the physical state of calcium present. The heat treatment should not be extensive, because due to extensive heat treatment, the viscosity of the product will be modified. (page 4, first and second paragraphs).

7. R1 teaches the decalcification of milk by ion exchange using cationic resins. Such resins can be charged for example by sodium, potassium, ammonium or hydrogen ion or by divalent ions such as magnesium, zinc, copper or trivalent ions depending on the salt concentration, pH and the desired composition of the material. (page 5, 3<sup>rd</sup> paragraph)

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8. R1 discloses that the decalcification can be 0-80% and preferably 20-40%. The decalcification extent will depend on the type of cheese desired (page 7, second paragraph).

9. R1 discloses that the decalcification is optionally associated with a heat treatment between 75-150C and preferably 90-110C. R1 restates that the decalcification together with heat treatment will allow obtaining a fine and homogenous texture of cheese. (page 7, 3<sup>rd</sup> paragraph). It is therefore clear that the cheese obtained by using heat treated, decalcified milk of R1 is nugget free as presently claimed.

10. R1 discloses that the calcium can be reintroduced by adding a calcium salt or by mixing at least one non-decalcified product such as milk. (page 7, 4<sup>th</sup>, 5<sup>th</sup> and 6<sup>th</sup> paragraphs). It is therefore clear that the calcium depleted, heat treated milk product of R1 is mixed with milk or other materials containing calcium to make the mixture suitable for rennet coagulation due to the presence of calcium ions.

11. R1 gives examples of making cheese using calcium depleted milk and rennet. Decalcification is carried out to 30% in Example 1 and to 100% in Example 2. In Example 3, heat treatment is carried out by injection of vapor at 120C. (pages 8-9). The cheese is subjected to further processing (Examples).

12. While R1 does not explicitly disclose a pH range at which whey proteins are heat denatured, the pH range as presently claimed is inherent to milk. R1 also discloses the heating process and attributes the favorable effect of the thermal process treatment to a partial denaturation of proteins. (page 4, lines 6-7). Therefore the limitation of heating the milk at pH 6.0-7.0 is anticipated by R1.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-9, 11-19 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhaskar et al. (WO 01/41578; hereinafter R2) in view of Delespaul et al. (FR 2 452 879; Official Translation; hereinafter R1).

15. R2 discloses the production of dried milk protein concentrates (MPC) which have been calcium depleted to an extent which allows improvements in the use of dried milk protein concentrates in cheese manufacture. The invention includes a method of cheese manufacture comprising a) dispersing in milk a dried MPC or MPI having at least 70% dry matter as milk proteins, b) treating the mixture with a coagulating enzyme to produce a curd, c) processing the curd to make cheese; Wherein the incorporation of calcium depleted MPC allows the manufacture of substantially nugget-free cheese. (Abstract).

16. R2 discloses the steps of incorporation of a dried MPC into milk and the subsequent cheese making process. (page 2, lines 8-15).

17. R2 discloses the extent of decalcification required as 20-100% depending on the milk protein content of the MPC. (page 2, lines 17-22)

18. R2 discloses the use of ion exchange, acidification and addition of chelating agents for the decalcification process. (page 3, lines 4-10).

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19. R2 discloses the drying process which can be done by standard drying processes. Drying may be preceded by dewatering . (page 4, lines 31-34)
20. R2 gives Examples of preparation of dried calcium depleted MPC (page 7) , the solubility of the dried product in water (page 9, Example 2), and processes for cheese preparation (page 9, Example 3).
21. R2 basically disclose most technical features of the presently claimed invention, however, R2 is silent regarding the heat treatment of the raw material for decalcification.
22. The disclosure of R1 is incorporated by reference as cited above.
23. R1 discloses that the decalcification is optionally associated with a heat treatment between 75-150C and preferably 90-110C. R1 restates that the decalcification together with heat treatment will allow obtaining a fine and homogenous texture of cheese. (page 7, 3<sup>rd</sup> paragraph).
24. While R1 discloses the temperature range at which the heat treatment can be carried out, and it specifically states that intensive denaturation of proteins will affect the viscosity of the product, it does not mention duration of heat treatment. However, knowing the temperature range and the disadvantage of overheating the mixture as taught by R1, one would obviously optimize the duration of heating for the milk mixture.
25. Given that R1 discloses the heating of the raw material to denature the whey proteins together with the effective temperature range, selecting the equipment and method for heat treatment of milk, as claimed in claim 19, is obvious to an ordinary skill in the art.

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26. In summary, R2 discloses the use of decalcified milk protein concentrate (MPC) in cheese making. R2 clearly teaches of the effect of decalcification and heat treatment of the milk raw material in producing mixtures which can be coagulated by rennet and resulting in cheese with homogenous texture (i.e. nugget free cheese). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow the teachings of R2 and R1 to prepare high yield MPC and MPI of the presently claimed invention and to make cheese free of nuggets which results in more consistent and efficient cheese making (page 1, lines 21-23, R2). Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in preparing calcium depleted milk concentrates and manufacturing cheese using the same.

### ***Response to Arguments***

Applicants arguments have been thoroughly reviewed. These arguments are not persuasive for the following reasons.

1. Mr. Anema states that prior to the present invention it was now known that reduced calcium MPC could be effective in preventing loss of the whey protein into the whey in a traditional cheese making process even if heat treated.

a. Delespaul (R1) clearly discloses the decalcification and heat treatment of milk products to make them suitable for cheese making. R1 further, teaches of the beneficial effect of decalcification and heat treatment of milk raw material on the homogenous texture of the cheese product .



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2. Mr. Anema states that Delespaul does not provide any teaching in that regard because Delespaul uses ultrafiltration to remove water from the cheese milk to avoid the necessity for separating whey from casein. Thus Delespaul does not separate the whey and provides no reason to use reduced calcium MPC to prevent loss of whey protein in a traditional cheese making process.

a. Delespaul makes a milk protein concentrate (MPC) by employing ultrafiltration. Delespaul further teaches that the milk material can be heated and decalcified before or after concentration using ultrafiltration. Delespaul also clearly states the beneficial effect of heat treatment and decalcification of the milk material on the homogenous cheese texture. Therefore, since the method of Delespaul comprises both heat treatment and decalcification of the milk material, the prevention of loss of whey proteins would be intrinsic in the cheese made with the decalcified, heat treated milk material of Delespaul. One of ordinary skill in the art would realize that the temperature range taught by Delespaul denatures the whey proteins. This denaturation results in their association with caseins leading to improved cheese yield and thus the prevention of loss of these proteins in the whey separated from rennet curd.

3. Applicants argue that Delespaul does not disclose adding the ultrafiltration retentate or a calcium depleted MPC to a milk containing fat or any other aqueous solution used as the starting material in claim 10.

a. Delespaul prepares a concentrated milk product (by ultrafiltration ) which has been heated and decalcified either before or after ultrafiltration process. Then Delespaul clearly states that “when the treatment leads to a total decalcification of the milk, of the

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retentate or other protein substances that can be coagulated by rennet, one again introduces a quantity of soluble calcium that is sufficient to allow the action of rennet and resulting coagulation.” Delespaul further states that “The calcium can be reintroduced by adding a calcium salt in appropriate proportions (for example, calcium chloride or monocalcium phosphate), OR MIXING AT LEAST ONE NON-DECALCIFIED PRODUCT CHOSEN FROM THE GROUP CONSISTING OF MILK.....and the proportions of non-decalcified and decalcified raw materials to be mixed ...” (page 7, paragraphs 3 and 4). Therefore, Delespaul anticipates mixing the milk protein concentrate with milk or any solution containing calcium as recited in claim 10, so that the mixture becomes suitable for coagulation with rennet.

4. Applicants argue that Bhaskar provides a method of making a dried MPC for use in conventional cheese making. In contrast the claimed processes allow for retention of the whey protein in the curd and subsequently the cheese.

a. The rejection of claims 1 and 11 is an obviousness type rejection involving the teachings of Bhaskar (R2) and Delespaul (R1). As detailed above, the heat treatment of the raw material is disclosed by R1 resulting in denaturation of whey proteins leading to their association with caseins. Therefore, the retention of whey proteins in the curd would be inherent in the heat treated milk material as disclosed by R1.

Furthermore, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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It is true the Bhaskar does not disclose the heating process, but that is the reason why Delespaul is cited. The combined teachings of R1 and R2 makes the claimed invention obvious.

Applicants should also realize that the ultrafiltration process disclosed by Delespaul is in fact the process for making milk protein concentrate (MPC), and therefore, the heat treatment disclosed by Delespaul is a part of making the MPC which is later used for cheese making.

5. Applicants argue that prior to the claimed invention, one would expect to see the heat treatment of Delespaul making the treated milk very viscous.

a. Delespaul, teaches of the consequences of over heating the treated mixture resulting in increased viscosity. However, it is obvious that the extent of heating would be a controllable step in order to prevent the viscosity increase.

6. Applicants argue that there would be no reasonable expectation of success for combination of Bahaskar and Delespaul.

a. It should be realized that claims 1 and 11 require a dried MPC. The MPC disclosed by Delespaul is not a dried MPC. Therefore, the decalcified, heated MPC of Delespaul is obviously dried and used as disclosed by Bhaskar.

Delespaul clearly discloses the use of decalcified and heat treated milk in making cheese with homogenous texture which is clearly the nugget free cheese as presently claimed.

***Conclusion***

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr  
Examiner  
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781